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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/031,478

07/29/2002

Kevin Jeffrey Barnham

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EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/031,478	<b>Applicant(s)</b> BARNHAM ET AL.	
	<b>Examiner</b> Andrew D. Kosar	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37 and 47-55 is/are pending in the application.
- 4a) Of the above claim(s) 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37 and 47-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendments/Arguments***

Applicant's amendments and arguments filed December 13, 2007 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Applicant has cancelled all original claims except claim 37, and has added new claims 47-55, drawn now to a method of solubilizing A $\beta$  deposited in the brain of Alzheimer's disease patients.

Applicant's new method is distinct from that previously claimed, having different outcomes and described/claimed end results, however because the examiner is unable to find support under 35 USC 112 1<sup>st</sup> ¶ for the new claimed method, the examiner has determined that in the interest of compact prosecution, the claims would be examined.

The previously cited references are still applicable under 35 USC §§ 102(b) and 103(a), the search has not been extended to new claim 55, drawn to Pt complexes, in that an election of species requirement was set forth, allowable subject matter was indicated and the search was extended. Applicant is reminded that the search need not be extended unnecessarily to cover non-elected species. Here, the prior art previously relied upon reads on new claims, and thus the search is not extended to the Pt complex species. Thus, claim 55 is withdrawn from consideration, there being no allowable generic or linking claim.

It should also be noted that it is unclear to the examiner why claim 37 has not been cancelled, as the claim from which it depended has been cancelled.

***Claim Rejections - 35 USC § 112***

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 47-54** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states that, “[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).” Further, the MPEP states, “[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

Here, the claims are now drawn to a method of solubilizing A $\beta$  deposits in the Alzheimer's patient, however there is no explicit, implicit or inherent support for this new claimed method. The previous claimed methods and as-filed disclosure provide inhibiting metal binding, however there is not discussion of deaggregation or solubilization of A $\beta$  deposits. Further, Applicant has provided no evidence of support for the new methods being claimed by reference to any specific example or passage in the as-filed disclosure.

**Claims 47-54** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated that, “To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated that, “A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by

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structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional

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characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.” MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to solubilizing  $\beta$ -amyloid peptide with a metal complex.

*(1) Level of skill and knowledge in the art:*

The level of skill and knowledge in the art is low, particularly with regards to the *a priori* knowledge of which metal complexes will, or will not, function in the methods as claimed.

*(2) Partial structure:*

The claims require that the compounds only be a metal complex. The specification provides no specific, or prophetic compounds that will function as claimed, showing only compounds that are asserted to inhibit metal binding. There is no discussion or examples of compounds, or structural requirements of compounds, that will effect solubilization.

*(3) Physical and/or chemical properties and (4) Functional characteristics:*

The compounds must be a metal complex and solubilize A $\beta$  deposits.

*(5) Method of making the claimed invention:*

Methods of making metal complexes are known to the artisan, however methods of making the myriad of compounds that will be capable of functioning as required in the claims is beyond that of the skilled artisan. There is no discussion in the specification of specific or

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prophetic compounds that will function as claimed, and thus one would not know how to make such compounds with the requisite activities.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 31-31, 44 and 45 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any metal complex. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus. The specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

**Claims 47-55** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting the binding of metal ions to  $\beta$ -amyloid peptide

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with BRI7161, BRI7159, BRI7158, BRI7080 or BRI7103 or the compounds specifically identified in the prior art, does not reasonably provide enablement for solubilization of A $\beta$  in Alzheimer's patients with any metal complex. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

*(1) The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to solubilization of A $\beta$  deposits in an Alzheimer's patient with a metal complex. The breadth of the claims is indeterminable, as the limitation of the method was not found in the as-filed disclosure.

*(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

The state of the art with regards to treating Alzheimer's is unpredictable.

WebMD (WebMD Alzheimer's Disease: treatment overview. Web document

<<http://my.webmd.com/content/article/71/81399.htm>> Accessed 2/22/05. 2 pages) teaches that,

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“there is no cure for Alzheimer’s disease and no proven way of slowing its progression. Because the exact cause of Alzheimer’s disease is unknown, there is also nothing that can be done to prevent it.” (page 1 of 2).

WebMD teaches that the approved drugs for treatment, “Aricept®, Exelon®, Reminyl®, and Cognex® seem to help only those with mild or moderate symptoms of Alzheimer’s disease; Namenda® is prescribed for patients who have moderate-to-severe Alzheimer’s.” (page 2 of 2). The approved drugs are all for slowing the breakdown of acetylcholine.

Further, ADEAR (ADEAR Alzheimer’s Disease Medications fact sheet. NIH Publication 03-3431. Alzheimer’s Disease Education & Referral Center. National Institute on Aging, NIH, US Dept HHS. July 2004. 6 pages) teaches that Aricept®, Exelon®, Reminyl®, and Cognex® are for mild to moderate Alzheimer’s disease (column 2), and Namenda® is for moderate to severe Alzheimer’s (column 3).

Although these compounds are approved for treating Alzheimer’s, Ballard (C Ballard, et al. Quetiapine and rivastigmine and cognitive decline in Alzheimer’s disease : randomized double blind placebo controlled trial. British Medical Journal. (2005) February 18, 5 pages) teaches that rivastigmine (Exelon®, supra), “seemed of no benefit in patients with dementia and agitation in institutional care,” and that qeutiapine “was associated with greater cognitive decline than placebo.” (page 4 of 5).

Furthermore, treating Alzheimer’s necessarily requires delivery of the therapeutic to the brain, however EVERTS (S. Everts, “Brain Barricade”. C& E News (2007), 85(23), pages 33-36, html copy, 6 pages) teaches, “Conditions of neurodegeneration are not well-served by current

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therapies, and they place a tremendous burden on our society,” and, “Crossing the BBB is certainly not impossible, but it remains a significant challenge.” (page 6 of 6).

*(5) The relative skill of those in the art, (6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

In view of the art, the level of skill in the art is low, such that one would not know which metal complex compounds would work in the methods as claimed. The specification has provided no actual or prophetic compounds useful in the method as claimed.

*(8) The quantity of experimentation necessary:*

Considering the state of the art as discussed by the references above, particularly with regards to treating Alzheimer’s and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 37, 53 and 54** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 depends from no cancelled claims, and thus lacks clear antecedent basis.

Claims 53 and 54 recite, “the targeting moiety...” which lacks antecedent basis. Claim 47 does not provide support for ‘the targeting moiety’.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

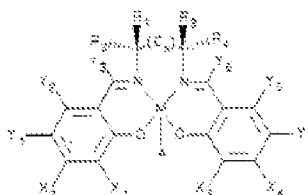
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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 47-51** are rejected under 35 U.S.C. 102(b) as being anticipated by MALFROY-CAMINE (WO 96/40148 A1).

The instant claims are presented *supra*. Malfroy-Camine teaches a method for preventing, arresting or treating a free radical-associated disease state by administration of a



salen metal complex of the general formula: (M=Mn, Co, Fe, V, Cr or

Ni) where the disease is Alzheimer's (e.g. claim 6). Because the compound meets the structural requirements and is administered to the same patient population, it inherently must function as claimed, i.e.- blocking binding of the metal ions to the  $\beta$ -amyloid peptide, etc. Additionally, please note, since the Office does not have the facilities for examining and comparing

Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

*See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 47-54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Malfroy-Camine, *supra*, in view of PARDRIDGE (US Patent 5,004,697).

The instant claims and teachings of Malfroy-Camine are presented *supra*.

Pardridge teaches modifying antibodies for delivery through the BBB for neuropharmaceuticals (e.g. Abstract, claims 6 and 9), specifically teaching that the antibody is for amyloid peptide of Alzheimer's disease (claim 9).

The difference between the instant claims and the teachings of Malfroy-Camine, is that while Malfroy-Camine teaches treating Alzheimer's with a metal salen complex, Malfroy-Camine does not teach coupling it with a targeting moiety.

It would have been obvious to have made and delivered the metal salen complex via coupling to an amyloid specific antibody in order to specifically deliver the salen complex to the Alzheimer's plaques it is used to treat. One would have been motivated to have coupled the salen to an antibody in order to deliver the salen complex efficiently to the point of need. One would have had a reasonable expectation for success in making a salen-antibody conjugate, as conjugation of antibodies to therapeutics is a technique widely practiced in the medicinal arts, particularly to cross the BBB (e.g. Saito, et al. PNAS (1995) 92, pages 10227-10231).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claim 55 drawn to an invention nonelected with traverse in the reply filed on January 10, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/  
Primary Examiner, Art Unit 1654

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